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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,527	05/19/2004	Theresa A. Hadlock	00786-446002	5575

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EXAMINER

JACKSON, GARY

ART UNIT PAPER NUMBER

3731

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/849,527

Applicant(s)

HADLOCK ET AL.

Examiner

Gary Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-43, 45-49 and 55-59 is/are rejected.
- 7) ☒ Claim(s) 5, 44 and 50-54 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/19/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.



DETAILED ACTION

This action is responsive to the present application that is a continuation of earlier application 09/774,397. The claims in this application are substantially the same as in the 09/774,397 application. Therefore, the action is repeated herein as in the last Office Action of said earlier application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stensaas et al. The patent to Stensaas et al discloses a nerve-regenerating conduit being in the form of a roll having a spiral of about one to 11 rotations to support the nerve endings. The applicants' specification is silent as to the criticality or benefits of having at least 3 % rotations of the conduit. Stensaas et al teach the concept of forming a spiraled conduit to secure the nerve ending without using sutures and other advantages. It would have been obvious to one having ordinary skill in the art to form Stensaas et al device of at least 3 % full rotations so as to tightly secure nerve endings in an end-to-end fashion. It is inherent that more than one full rotation will securely hold the nerve ends in the desired fashion.

Claims 2-3, 8-18, 40-43, 45-46 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al in view of Stensaas et al, Goosen et al (US Patent 4,806,355) and Hadlock et al publication "ECA Polymer Foam Conduit Seed with Schwann Cells Promotes Guided Peripheral Nerve Regeneration". Again, Butler

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discloses a method for regenerating nerves with use of a cell-encapsulating device.

Stensaas et al teaches the use of a rolled device for regenerating nerves. Hadlock et al discloses providing cells suspended in nerve regeneration conduit. Goosen suggest encapsulating cells.

It would have been within the purview of one having ordinary skill in the to provide Butler with the spiral roll device of Stensaas et al so as to wrap the nerve ends for tighter grip rather than inserting the ends into a grip. See figure 7A of Stensaas et al. In the alternative, it would have been obvious to one having ordinary skill in the art to provide Stensaas et al with an encapsulated layer of cells to promote nerve regeneration.

Claims 19-39, 47-49 and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stensaas in view of Butler, Goosen and Hadlock in further in view of Dionne et al (US Patent 5,773,286). The latter reference suggests encapsulating neurotrophic agents in separate spheres. It would have been obvious to one having ordinary skill in the art to provide Stensaas et al in combination with Butler, Goosen and Hadlock with encapsulated neurotrophic agents to promote nerve growth.

Allowable Subject Matter

Claims 5, 44 and 50-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

This is a continuation of applicant's earlier Application No. 09/774,397. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (571) 272-4697. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Antoine Nguyen can be reached on (571) 272-4693. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Jackson
Primary Examiner
Art Unit 3731

A handwritten signature in cursive script that reads "Gary Jackson".

gj
May 16, 2005